

***Remarks***

***I. Status of the Claims and the Specification***

Upon entry of the foregoing amendments claims 1, 2, 8, 10, 12, 14, 15, 17, 18, 19, 21, 24, 25, 27, 30, 33, 35, 42, 48, 49, 97, 111 and 113-118 are pending in the application, with claims 1 and 114 being the independent claims. Pending claims 4, 6, 7-11, 49, 94-96, 98-99, 102-104, 108-110 and 112 have been withdrawn from consideration by the Examiner as allegedly not being directed to an elected species.

Claims 8, 42, 48 and 104 are sought to be amended. The amendments to claims 42 and 104 are sought to correct claim dependencies and do not introduce new matter and their entry and consideration are respectfully requested. Support for amended claims 8 and 48 is found in paragraphs [0054-0056] of the present specification (U.S. published application 2006/0210588).

New claims 113-118 which are sought to be added are supported by the originally filed claims and specification including, *inter alia*, paragraphs [0098], [0215], [0251], [0252] and [0253] of the present specification (U.S. published application 2006/0210588). Accordingly, these new claims do not introduce new matter. Applicants therefore respectfully request the entry and consideration of new claims 113-118.

***II. Summary of the Office Action***

In the Office Action of May 11, 2007 (hereinafter “the Office Action”), at page 2, the Examiner has acknowledged Applicants’ election of restriction groups and species. However the Examiner did not find Applicants’ traversal of the Examiner’s restriction and election requirement persuasive.

At page 4 of the Office Action, the Examiner has rejected claims 1, 42 and 48 under the second paragraph of 35 U.S.C. § 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

At pages 5-7, claims 1, 2, 8, 12, 14, 15, 17, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bachmann et al. (U.S. Application No. 2003/0099668, filed September 16, 2002, with priority to September 14, 2001 and April 22, 2002, hereinafter “the ‘668 application”).

At pages 7-8, claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bachmann et al. (U.S. Application No. 2004/0005338, filed June 20, 2003, with priority to June 20, 2002, hereinafter “the ‘338 application”).

At pages 8-9, claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42 and 48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 14-16, 41, 48 and 55 of copending application 10/563,944 (hereinafter “the ‘944 application”).

In view of the following remarks, Applicants traverse the Examiner’s objections and rejections, and respectfully request that they be reconsidered and withdrawn.

### ***III. Election/Restriction***

The Examiner has withdrawn from consideration claims 4, 6, 7-11, 49, 94-96, 98-99, 102-104, 108-110 and 112 as being drawn to nonelected species. Withdrawn claims 4, 6, 7-11, 49, 94-96, 98-99, 102-104, 108-110 and 112 remain pending. Applicants

request that these withdrawn pending claims be rejoined, examined and allowed upon identification of allowable subject matter in generic or linking claims in accordance with 37 C.F.R. § 1.141(a).

Additionally, on the front page of the Office Action, the Examiner has withdrawn from consideration claims 8 and 10 as being drawn to nonelected species. However, in the Reply to the Restriction Requirement with Election of Species, Applicants clearly indicated that claims 8 and 10 read on the elected species. Thus, Applicants respectfully request the Examiner to rejoin and examine claims 8 and 10 with the currently elected group of claims.

#### ***IV. Obviousness-Type Double Patenting***

At pages 8-9, claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42 and 48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 14-16, 41, 48 and 55 of copending application 10/563,944 ("the 944 application").

Applicants would like to draw the Examiner's attention to MPEP § 1490.V.D. which states that:

If two (or more) pending applications are filed, in *each* of which a rejection of one claimed invention over the other on the ground of provisional obvious-type double patenting (ODP) is proper, the ODP rejection will be made in each application. If the ODP rejection is the only rejection remaining in the earlier filed application of the two pending applications, (but the later-filed application is rejectable on other grounds), the examiner should then withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

The priority date of the '944 reference application used in making this obviousness-type double patenting rejection is four months *after* the priority date of the present application. Applicants believe that the amendments and arguments presented herein will place the present application in condition for allowance except for the ODP rejection. Thus, Applicants request the Examiner to hold this rejection in abeyance until the arguments and amendments herewith have been considered, and to withdraw this rejection upon allowance of the present claims, in accordance with MPEP § 1490.V.D.

***V. Rejection under 35 U.S.C. § 112***

At page 4 of the Office Action, the Examiner has rejected claims 1, 42 and 48 under the second paragraph of 35 U.S.C. § 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

In making the rejection to claims 8 and 48, the Examiner states that "It is not clear if applicants intend the two polypeptides to be bound to each other directly or by way of a linking sequence or bound to the VLP directly or by way of a linking sequence."

Solely to advance prosecution and not in acquiescence to the Examiner's rejection, Applicants have amended claims 8 and 48 to include "wherein said at least two HIV polypeptides are bound to each other directly or by way of a linking sequence" and "wherein said at least two epitopes are bound to each other directly or by way of a linking sequence," respectively.

Amended claim 8 further defines the feature antigen of claim 1 to be the combination of at least two HIV polypeptides, wherein said at least two HIV polypeptides are bound to each other directly or by way of a linking sequence. It is intended that the two HIV polypeptides are bound to each other directly or by way of a linking sequence. This intention would be clear to one of ordinary skill from, *inter alia*, paragraph [0056] of the published application US2006/0210588. Paragraph [0056] defines the term "HIV polypeptide," in which, "Polyepitope," as one of the preferred embodiments of HIV polypeptide, refers to a combination of at least two HIV polypeptides, wherein said at least two HIV polypeptides are bound directly or by way of a linking sequence. As paragraph [0056] defines solely the antigen, not the relationship between the antigen and the virus-like particle, the wording "bound to each other directly or by way of a linking sequence" refers to the relationship of two HIV polypeptides, which after the binding still remain as antigen.

Claim 48 also further defines the feature antigen of claim 1. Amended claim 48 requires that when the antigen is a combination of at least two epitopes, said at least two epitopes are bound directly or by way of a linking sequence. Here it is also intended that said at least two epitopes bound to each other directly or by way of a linking sequence, wherein the resulting entity remains as antigen. This intention would be clear to one of ordinary skill from, *inter alia*, paragraph [0054-0056] of the published application US2006/0210588. Paragraph [0054] defined the term "Epitope" and paragraph [0055] states that preferred epitopes are the HIV polypeptides are the HIV polypeptides of the invention. Paragraph [0056] is described above. One of ordinary skill in the art would understand that that said at least two epitopes of claim 48 are bound directly to each

other or by way of a linking sequence, wherein the resulting entity remains as antigen. Applicants respectfully request that the rejection to claims 8 and 48 be withdrawn.

Claim 42 was rejected under the second paragraph of 35 U.S.C. § 112 as lacking sufficient antecedent basis in the therein recited claim 30 for the limitation "said palindromic sequence." This defect has been corrected by reciting claim 33 in the currently amended claim 42. Applicants respectfully request that the rejection to claim 42 be withdrawn.

***VI. Rejections under 35 U.S.C. § 102(e)***

***(a) Claims 1, 2, 8, 12, 14, 15, 17, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are not being anticipated by the '668 application***

In the Office Action at pages 5-7, claims 1, 2, 8, 12, 14, 15, 17, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are rejected under 35 U.S.C. § 102(e) as being anticipated by the '668 application.

As the Examiner has indicated at page 5 of the Office Action, the present rejection under 35 U.S.C. § 102(e) may be overcome by a showing under 37 C.F.R. § 1.132. To this end, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by Martin Bachmann, Alain Tissot and Edwin Meijerink, who are inventors common to the '668 application and to the present application. The Declaration states that the subject matter common to both applications was invented solely by Martin Bachmann Alain Tissot and Edwin Meijerink. Thus the disclosure of the subject matter in the '668 application which is claimed in the present application but not in the '668 application

does not qualify as an invention “by another” for the purposes of 35 U.S.C. § 102(e). Thus, Applicants respectfully request this rejection be reconsidered and withdrawn.

***(b) Claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are not being anticipated by the ‘338 application***

In the Office Action at pages 7-8, claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are rejected under 35 U.S.C. § 102(e) as being anticipated by the ‘338 application.

As the Examiner has indicated at page 7 of the Office Action, the present rejection under 35 U.S.C. § 102(e) may be overcome by a showing under 37 C.F.R. § 1.132. To this end, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by Martin Bachmann, who is the inventor common to the ‘338 application and to the present application. The Declaration states that the subject matter common to both applications was invented solely by Martin Bachmann. Thus the disclosure of the subject matter in the ‘338 application which is claimed in the present application but not in the ‘338 application does not qualify as an invention “by another” for the purposes of 35 U.S.C. § 102(e). Thus, Applicants respectfully request this rejection be reconsidered and withdrawn.

***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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